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EXAMINER	
WEISZ, DAVID G	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,345	HAUPT ET AL.	
	Examiner	Art Unit	
	DAVID WEISZ	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 August 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050610*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 4, 10, 13, 17, 19-22, 24, 27, 35 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad recitation “a mould surface”, and the claim also recites “preferably of metal such as steel, bronze, beryllium-copper alloy, or moulding die aluminum alloy" which is the narrower statement of the range/limitation. Additionally, claim 1 recites the broad recitation “moulding material”, and the claim also recites “preferably being a thermo plastic, more preferably a thermo plastic selected from the group comprising PS, PC, PMMA, COC, PP, PETG, PE, PA, ABS, POM, FUR, PVC, and TOPAS" which is the narrower statement of the range/limitation.

Claim 2 recites the broad recitation “metal”, and the claim also recites “preferably nickel; metal alloy, preferably steel; semiconductor, preferably silicon; ceramic, preferably alumina" which is the narrower statement of the range/limitation.

Claim 4 recites the broad recitation “an elastic metal”, and the claim also recites “preferably rubber" which is the narrower statement of the range/limitation.

Claim 10 recites the broad recitation “an elastic metal”, and the claim also recites “preferably a rubber, or nylon" which is the narrower statement of the range/limitation.

Claim 13 recites the broad recitation “moulding”, and the claim also recites “preferably injection moulding, more preferred compression injection moulding" which is the narrower statement of the range/limitation.

Claim 17 recites the broad recitation “surface treatment”, and the claim also recites “preferably by a physical and/or chemical treatment, more preferably by plasma treatment, heat treatment, corona discharge treatment, gaseous combustion treatment, irradiation treatment; or by surface coating, preferably by plasma polymerisation deposition, and/or metallization" which is the narrower statement of the range/limitation.
Claim 19 recites the broad recitation “an insert”, and the claim also recites “preferably a MEMS component, more preferably a micro-structured chip, a printed circuit board; an adhesive layer; and an intermediate layer, preferably a membrane, sheet, or toil" which is the narrower statement of the range/limitation.

Claim 20 recites the broad recitation “fixed”, and the claim also recites “preferably by incorporation therein or adhesion thereto" which is the narrower statement of the range/limitation.

Claim 21 recites the broad recitation “flexible membrane”, and the claim also recites “preferably rubber" which is the narrower statement of the range/limitation.

Claim 22 recites the broad recitation “micro-structured open cavity”, and the claim also recites “preferably a well or channel" which is the narrower statement of the range/limitation.

Claim 24 recites the broad recitation “fluidic coupling means”, and the claim also recites “preferably a coupling means comprising a luer-lock system, in particular a luer

for soft tubing, most preferred a integral fluidic coupling means" which is the narrower statement of the range/limitation.

Claim 27 recites the broad recitation “structure for display of information”, and the claim also recites “preferably one or more identification marks, such as well code marks, or tube connector numberings" which is the narrower statement of the range/limitation.

Claim 35 recites the broad recitation “fluidic cavities or cavity systems”, and the claim also recites “preferably a fluid conduit, a closed fluid channel, a fluid reservoir, or combinations thereof" which is the narrower statement of the range/limitation.
Claim 40 recites the broad recitation “micro-fluidic functions”, and the claim also recites “preferably fluidic conduit coupling means" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 11-39** are rejected under 35 U.S.C. 102(b) as being anticipated by Woudenberg et al. (US 6126899).

Regarding claim 11, Woudenberg discloses a micro-fluidic structure element, the element comprising a first outer face and a second outer face, said first and/or said second outer face comprising at least one micro-structure for at least one micro-fluidic function (Figure 9), and said first and said second outer faces being in fluid communication by at least one through-going aperture (162).

Regarding claim 12, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first and second outer faces are substantially orthogonal (Figure 9) to said through-going aperature (162).

Regarding claim 13, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein the element is prepared by moulding, preferably by injection moulding (C11/L4-10).

Regarding claim 14, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein the element is in the form of a monolithic element (C11/L1-4).

Regarding claim 15, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein the element is composed by two or more structure elements (C11/L1-4).

Regarding claim 16, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first and second outer faces comprisesly or partly functionalized surfaces (Figure 8).

Regarding claim 17, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said wholly or partly functionalized surfaces have been functionalized by surface treatment (C11/L29-33).

Regarding claim 18, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first and/or second outer face comprising at least one additional element (C11/L29-33).

Regarding claim 19, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said at least one additional element is an adhesive layer (C11/L29-33).

Regarding claim 20, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said at least one additional element is fiexed to said first and/or second outer faces (C11/L29-33).

Regarding claim 21, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said additional element comprises a material selected from the group consisting of a metal (C11/L29-33).

Regarding claim 22, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said at least one

through-going aperture is in fluid communication with a micro-structured open cavity (Figure 9, C14/L25-35).

Regarding claim 23, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first outer face and/or said second outer face comprises one or more open structures in the millimeter range (C14/L25-35).

Regarding claim 24, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first outer face and/or second outer face comprises a fluidic coupling means for coupling to an external fluid conduit (200).

Regarding claim 25, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first outer face and/or said second outer face comprises at least one micro-structure for at least one non-micro-fluidic function (C6/L34-37).

Regarding claim 26, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first outer face and/or said second outer face comprises at least one micro-structure for at least one non-micro-fluidic function (C6/L34-37).

Regarding claim 27, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said at least one non-micro-fluidic function comprises a structure for display of information, prefereably one or more identification marks, such as well code marks, or tube connector numberings (C6/L34-37).

Regarding claim 28, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said at least one non-fluidic function comprises a positioning structure for positioning and temporary fixation of a cover element (C5/L63-67).

Regarding claim 29, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said first outer face

and/or said second outer face comprises at least one micro-structure providing a lab-on-a-chip function (C22/L6-45).

Regarding claim 30, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein said lab-on-a-chip function is sample delivery to a sensor (C22/L6-45).

Regarding claim 31, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the element wherein the element is substantially planar (Fig 7-9).

Regarding claim 32, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the micro-fluidic structure comprising at least one micro-fluidic structure element and at least one cover element; said first and/or second outer faces of said at least one micro-fluidic structure element being wholly or partly covered by said at least one cover element. (See figures 7-9).

Regarding claim 33, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the structure wherein said at least one cover element is micro-structured (Figure 8).

Regarding claim 34, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the structure wherein said at least one micro-fluidic structure element and/or said at least one cover element comprises mating means for positioning thereof with respect to each other. (C5/L63-67).

Regarding claim 35, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the structure wherein said at least one micro-fluidic structure element and said at least one cover element form one or more fluidic cavities or cavity systems (Figure 8).

Regarding claim 36, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the structure wherein said at least one cover element comprises wholly or partly an element exhibiting optical transparency (C2/L42-46).

Regarding claim 37, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the structure wherein said cover element comprises PS (C10/L60-67).

Regarding claim 38, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the structure wherein said fluidic cavity wholly or partly exhibits a cross section of polygons being constant in depth and width (Figure 9).

Regarding claim 39, Woudenberg discloses all of the claim limitations as set forth above. Additionally, the reference discloses the structure wherein said at least one cover element is substantially planar (Figures 7 and 8).

5. **Claims 7-9** are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki (US 4645443).

Regarding claim 7, Aoki discloses a mould assembly for moulding a micro-structured element of a micro-fluidic structure (Figure 1), said mould assembly comprising:

(a) a first mould die (1);

(b) a second mould die (2);

(c) an adjustable support for supporting said first and said second mould dies for relative movement towards and away from each other between a closed and an open mould position (6);

(d) said first or second mould dies comprising at least one core pin engaging said other of said first and second mould dies in said closed position;
wherein said first and/or second mould dies comprise a wholly or partly micro-structured mould surface (6).

Regarding claim 8, Aoki discloses all of the claim limitations as set forth above. Additionally, the reference discloses the mould assembly wherein said micro-structured mould surface comprises engagement means for engaging said at least one core pin (6).

Regarding claim 9, Aoki discloses all of the claim limitations as set forth above. Additionally, the reference discloses the mould assmbly wherein said engagement means comprises a protrusion of said microstructured mould surface (Figure 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 1-6 and 40-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hergenroeder (WO 0077509) in view of Lundquist (US 4452420).

Regarding claim 1, Hergenroeder discloses a method of producing a micro-fluidic structure element, the method comprising:

(a) providing a mould assembly for moulding a micro-structured element; said mould assembly comprising a first and second mould die together forming a die cavity (P11/L30 to P12/L26), said first and/or said second mould die comprising: (i) a mould surface, preferably of metal such as steel, bronze, beryllium-copper alloy, or moulding die aluminium alloy, comprising a micro° structured mould surface (P11/L30 to P12/L26), and

(b) applying a moulding material to said die cavity, said moulding material preferably being a thermo plastic, more preferably a thermo plastic selected from the group comprising PS, PC, PMMA,COC, PP, PETG, PE, PA, ABS. POM, FUR, PVC, and TOPAS (P10/L10-30);

(c) allowing said moulding material to consolidate (P10/L10-30); and

(d) ejecting said consolidated moulding material from the die cavity (P10/L10-30).

However, the reference does not disclose one or more core pins extending between said first and second mould die across said die cavity.

Lundquist discloses an injection mould, wherein one or more core pins extending between said first and second mould die across said die cavity (Abstract). Additionally, the reference discloses that using such a pin permits the inner face and second face to have zero clearance with dimensional changes of the mould (Abstract).

Hergenroeder and Lundquist are analogous because both references are directed toward injection moulds with opposing members.

It would have been obvious to one having ordinary skill in the art at the time of the invention to use the pin of Lundquist in the mould of Hergenroeder because using such a pin permits the two mould members to have a zero clearance with dimensional changes of the mould.

Regarding claim 2, modified Hergenroeder discloses all of the claim limitations as set forth above. Additionally, the reference discloses the method wherein said mould is comprised of metal (P11/L22-28).

Regarding claim 3, modified Hergenroeder discloses all of the claim limitations as set forth above. Additionally, the reference discloses the method wherein one of said

first and second mould dies comprises a microstructured mould surface (P12/L28-P13/L2).

Regarding claim 4, modified Hergenroeder discloses all of the claim limitations as set forth above. Additionally, the reference discloses the method wherein one or more core pins comprise a mechanical spring (see Lundquist, Abstract).

Regarding claim 5, modified Hergenroeder discloses all of the claim limitations as set forth above. Additionally, the reference discloses the method wherein said first or second mould die comprises a releasable structural element to be released into said moulding material during application or consolidation thereof (P12/L28-P13/L2).

Regarding claim 6, modified Hergenroeder discloses all of the claim limitations as set forth above. Additionally, the reference discloses a micro-fluidic structure element obtainable by the above method (P12/L28-P13/L2).

Regarding claim 40, modified Hergenroeder discloses all of the claim limitations as set forth above. Additionally, the reference discloses a method of producing a standardized micro-fluidic structure element, the element comprising a standard face and a use-adapted face having at least one predetermined micro-structure for at least one predetermined micro-fluidic function, the micro-fluidic functions of the standard face being in fluid communication with the at least one predetermined micro-fluidic function on the use-adapted face (P12/L28-P13/L2), the method comprising:
(a) providing a mould assembly for moulding a micro-structured element (P12/L28-P13/L2), said mould assembly comprising:
(i) a first and second mould die forming a die cavity, said first mould die comprising a micro-structured and/or macro-structured mould surface of the predetermined number of micro-fluidic functions of the standard face and; and second mould die comprising a micro-structured and/or macro-structured mould surface of the at least one predetermined micro-fluidic function of the use-adapted face (P12/L28-P13/L2);
(ii) one or more core pins extending between said first and second mould die across said die cavity (Lundquist, Abstract);
(b) applying a moulding material to said die cavity (P10/L10-30);

(c) allowing said mouldinq material to consolidate (P10/L10-30); and
(d) ejecting said consolidated moulding material from the die cavity (P10/L10-30).

Regarding claims 41 and 42 modified Hergenroeder discloses all of the claim limitations as set forth above. Additionally, the reference discloses the above method of producing a micro-fluidic system (P12/L28-P13/L2). Additionally, said micro-fluidic system can have lab-on-a-chip operation of protein synthesis (P12/L28-P13/L2 as evidenced by Woudenberg et al. US6126899, C22/L6-45).

9. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki (US 4645443) as applied to claims 7-9 above in view of Lundquist (US 4452420).

Regarding claim 10, Aoki discloses all of the claim limitations as set forth above. However, the reference does not disclose one or more core pins comprising a mechanical spring.

Lundquist discloses an injection mould, wherein one or more core pins comprise a mechanical spring (Abstract). Additionally, the reference discloses that using such a pin permits the inner face and second face to have zero clearance with dimensional changes of the mould (Abstract).

Aoki and Lundquist are analogous because both references are directed toward injection moulds with opposing members.

It would have been obvious to one having ordinary skill in the art at the time of the invention to use the pin of Lundquist in the mould of Aoki because using such a pin permits the two mould members to have a zero clearance with dimensional changes of the mould.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID WEISZ whose telephone number is (571)270-7073. The examiner can normally be reached on Monday - Thursday, 7:30 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1/5/2009

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

/D. W./
Examiner, Art Unit 1797